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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/627,642	07/28/2003	Makoto Hirata	P65588US1	3596
136	7590	08/06/2004	EXAMINER KEYS, ROSALYND ANN	
JACOBSON HOLMAN PLLC 400 SEVENTH STREET N.W. SUITE 600 WASHINGTON, DC 20004			ART UNIT 1621	PAPER NUMBER

DATE MAILED: 08/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center">Office Action Summary</p>	Application No. 10/627,642	Applicant(s) HIRATA ET AL.	
	Examiner Rosalynd Keys	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claim

1. Claims 26-31 are pending.
Claims 26-31 are rejected.
Claims 1-25 are cancelled.

Priority

2. Applicant has now complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120.

Claim Rejections - 35 USC § 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 26-31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility.

Claims 26-31 do not have a substantial asserted utility because they are directed to an intermediate product (compound (4)) for use in making a final

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product (compound 1) that has no specific, substantial and credible utility. An intermediate, which is useful to make another intermediate, is not a practical (substantial) utility. See *Bindra v. Kelly*, 206 USPQ 570 (BdPatApp&Int 1979) and MPEP 2107.01 and 2138.05.

Claims 26-31 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial/practical asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Amendment

Specification

6. The objection to the abstract is withdrawn, due to the amendment filed July 21, 2004.

7. The objection to the specification is withdrawn.

Claim Rejections - 35 USC § 102

8. The rejection of claim 25 under 35 U.S.C. 102(a) as being anticipated by Engel et al. (US 5,710,145) is withdrawn due to the cancellation of said claim. Engel et al do not anticipate new claims 26-31 because Engel et al. do not teach or fairly suggest a compound having the formula (4) as now presented.

Response to Arguments

9. Applicant's arguments filed July 21, 2004 have been fully considered but they are not persuasive.

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The Applicants argue that reliance on *Bindra* is misplaced because *Bindra* had nothing to do with whether utility as an intermediate is a practical utility under the statute. The Examiner disagrees. In *Bindra* the court stated:

"...Here, the subject matter in issue concerns a compound, Compound I, which is an intermediate useful in the preparation of a second intermediate, Diol III, which has admitted utility in the preparation of a known pharmaceutical, the prostaglandin analog. It may well be that, given the motivation, it would have been obvious, in the sense of 35 USC 103, to prepare Diol III from Compound I via the Grignard route. Viewed in its best light, the testimony of Kelly's experts, Axen and Gall, establishes that it was logical to anticipate with a high degree of probability that a trial of it would be successful. See *In re Kronig*, 539 F.2d 1300, 190 USPQ 425 (CCPA 1976); *In re Pantzer*, 52 CCPA 1135, 341 F.2d 121, 144 USPQ 415 (1965); *In re Moreton*, 48 CCPA 928, 288 F.2d 940, 129 USPQ 288 (1961). However, this is not the test for a reduction to practice. In *re Scheiber*, 587 F.2d 59, 199 USPQ 782 (CCPA 1978).

[8] We know of no controlling authority which supports the proposition that given a compound of known chemical structure, coupled with a strong probability that it could participate in a reaction to produce a compound of known utility, the requirement for establishing the practical utility requirement for a reduction to practice is satisfied. *Kawai v. Metlesics*, *supra*. Probable utility does not establish practical utility. Practical utility can, in our view, be established only by actual testing therefor, or by establishing such facts as would be convincing that such utility could be "foretold with certainty." *Blicke v. Treves*, *supra*, 112 USPQ at 475.....".

As in *Bindra*, the instant claims are directed to an intermediate, compound (4), which is useful for the preparation of a second intermediate, compound (1), which has admitted utility in the preparation of a known antidiabetic having protein kinase' C inhibiting activity. in view of the discussion above in *Bindra*, the

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instant compound (4) has only probable utility and not a practical utility, since the Applicants have not shown practical utility by actual testing or by establishing such facts as would be convincing that such utility could be foretold with certainty. See MPEP 2138.05, in particular the section entitled **A PROBABLE UTILITY MAY NOT BE SUFFICIENT TO ESTABLISH UTILITY**.

For the above reasons the instant claims 26-31 are not patentable.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone

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number is 571-272-0639. The examiner can normally be reached on M, R and F 3:30-8:30 pm and T-W 5:30-10:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Rosalyn Keys
Primary Examiner
Art Unit 1621

August 5, 2004